K030490

AUG 2 0 2003

510(k) Summary

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

Indications for use:

ISM1+

For culture of embryos. To be used in culture after fertilization in Universal IVF Medium (K 991279) up to Day3 to 6- to8-cell stage, followed by extended culture in ISM2+ or by transfer in UTM+.

ISM2+

For culture of embryos. To be used in culture from 6- to 8-cell stage on Day3 to blastocyst stage on day 5, followed by transfer in UTM+. ISM2+ shall be used after ISM1+.

UTM+

For transfer of embryos cultured in ISM1+ or ISM2+.

Composition:

ISM1+	ISM2+	UTM+
▪ Physiological salts	▪ Physiological salts	▪ Physiological salts
▪ Sodium bicarbonate	▪ Sodium bicarbonate	▪ Sodium bicarbonate
▪ Penicillin/Streptomycin	▪ Penicillin/Streptomycin	▪ Penicillin/Streptomycin
▪ HSA	▪ HSA	▪ HSA
▪ Glucose and derived metabolites	▪ Glucose and derived metabolites	▪ Glucose and derived metabolites
▪ Nucleosides	▪ Nucleosides	▪ Nucleosides
▪ Non-essential amino acids	▪ Non-essential amino acids	▪ Non-essential amino acids
▪ Essential amino acids	▪ Essential amino acids	▪ Essential amino acids
▪ Phenol Red	▪ Phenol Red	▪ Phenol Red
▪ Vitamins	▪ Vitamins	▪ Vitamins
		▪ Hyaluronate

Stability, cytotoxicity- and biocompatibility testing

Stability testing of ISM1+/ ISM2+/UTM+ sequential media has been performed for 17 weeks and a shelf life of 8 weeks from shipment date is recommended. Once opened the product is to be used within 28 days.

Furthermore UTM+ was classified as non-toxic according to the Mouse Embryo test, non-irritant according to vaginal irritation test and showed no evidence of delayed contact hypersensitivity.

Product testing controls

1. Sterility
2. pH
3. Osmolality
4. Endotoxin ≤ 0.1 EU/ml
5. Mouse Embryo Assay, ISM1+ and ISM2+ (one cell assay, Blastocyst rate > 70 %), UTM+ (two cell assay, blastocyst rate > 80 %)

For each batch a Certificate of Analysis with the results of the above tests is available.

Clinical Documentation:
Medi-Cult's new ISM1+, ISM2+(Innovative Sequential Media) and UTM + (Uterine Transfer Medium) is a modified version of older ISM1/ISM2/UTM media.

The original ISM media have been tested in a multicenter trial in France. The study included patients, not more than 40 years of age, accepted for IVF and ICSI treatments to a total of 466 cycles. After fertilization in Universal IVF Medium the embryos were cultured in ISM1, ISM2 and either transferred on Day 2/3 or Day 5 using UTM.The data show that the ISM media support development of viable cleavage and blastocyst embryos following either IVF or ICSI and these can be transferred on Day 2/3 or at the blastocyst stage.

All pregnancies in the study were singletons with the exception of one pair of twins. The twins were a result of two individual embryos implanted and therefore no monozygotic twins were seen in the entire study.

Furthermore, a clinical study has been performed where Medi-Cult's original ISM1/ISM2 have been compared to ISM1+/ISM2+. The conclusion was that the two versions were equally effective.

Two prospective studies where the ISM series and ISM+ series respectively have been compared to G1.2/G2.2 media systems have been performed.

Based on the results of these studies it is concluded that Medi-Cult's ISM+ series comprising ISM1+, ISM2+ and UTM+ media are substantial equivalent to Vitrolife's G1.2-G2.2 sequential culture system and is effective for development of embryos for Day 2-3 transfer or for developing blastocysts for Day 5 transfer in patients for IVF or ICSI

During our studies there has been no registered complaints and no evidence that the product has been the cause of any serious adverse events in connection with its intended use.

Thus based on the clinical data presented and our experience with the ISM products we feel that the safety and effectiveness of the product for its intended use is shown in the present submission and the products are substantially equivalent to the predicated devices G1.2 media (K 000625) and G2.2 media (K 000619).

Prepared and Submitted by:

02-13-03

Ronald G. Leonardi, Ph.D. Date
President
R & R REGISTRATIONS
P.O. Box 262069 San Diego, Ca 92131
619-586-0751

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2003

Medi-Cult a/s
% Ronald G. Leonardi, Ph.D.
President
R & R Registrations
P.O. Box 262069
SAN DIEGO CA 92196-2069

Re: K030490
Trade/Device Name: Innovative Sequential Media System (ISM1™, ISM2™) and Uterine Transfer Medium (UTM™)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: June 11, 2003
Received: June 11, 2003

Dear Dr. Leonardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K030490

Device Name: ISM1+™, ISM2+™ and UTM+™

INDICATIONS FOR USE:

ISM1+
For culture of embryos. To be used in culture after fertilization in Universal IVF Medium (K 991279) up to Day 3 to 6- to 8-cell stage, followed by extended culture in ISM2+ or by transfer in UTM+.

ISM2+
For culture of embryos. To be used in culture from 6- to 8-cell stage on Day 3 to blastocyst stage on Day 5, followed by transfer in UTM+. ISM2+ shall be used after ISM1+.

UTM+
For transfer of embryos cultured in ISM1+ or ISM2+.

(PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030490